NDA 10-515/S-023 **FEB 23 2000**

Abbott Laboratories
Attention: Ms. Leslie Koehier
200 Abbott Park Road
D-389, Bldg. AP30
Abbott Park, Illinois 60064-6157

Dear Ms. Koehier:

Please refer to your supplemental new drug application dated September 11, 1998, received September 16, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isuprel (isoproterenol hydrochloride) Injection.

We acknowledge receipt of your submission dated November 12, 1999 that constituted a complete response to our September 29, 1999 action letter.

This supplemental new drug application provides for final printed labeling revised to create under **PRECAUTIONS,** a new **Geriatric** Use subsection that reads as follows:

> Clinical studies of Isuprel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects in clinical circumstances. There are, however, some data that suggest that elderly healthy or hypertensive patients are less responsive to beta-adrenergic stimulation than are younger subjects. In general, dose selection for elderly patients should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant diseases or other drug therapy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your submission dated November 12, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Project Manager
(301) 594-5313

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research